



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License: Development of Human Monoclonal Antibodies Against DR4**

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to practice the inventions embodied in PCT Patent Application No. PCT/US2011/040750 and foreign equivalents thereof entitled “Agonistic Human Monoclonal Antibodies Against DR4” (HHS Ref. No. E-158-2010/0) to Customized Biosciences, Inc., which is located in Pasadena, CA. The patent rights in these inventions have been assigned to the United States of America.

The prospective start-up exclusive commercial license territory may be worldwide and the field of use may be limited to “use of the Licensed Patent Rights to develop therapeutic agents for the treatment of lymphomas, leukemias, hepatocellular cancer, colorectal cancer, ovarian cancer, lung cancer, rheumatoid arthritis, systemic lupus

erythematosus, multiple sclerosis, amyotrophic lateral sclerosis, and Alzheimer's disease".

**DATE:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

**ADDRESS:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Whitney A. Hastings, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; E-mail: [hastingw@mail.nih.gov](mailto:hastingw@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The tumor necrosis factor (TNF)-related apoptosis-inducing ligand (TRAIL) and its functional receptors, DR4 and DR5, have been recognized as promising targets for cancer treatment. Therapeutics targeting TRAIL and its receptors are not only effective in killing many types of tumors but they also synergize with traditional therapies, and show efficacy against tumors that are otherwise resistant to conventional treatments.

The above identified patent application relates to the development of two human monoclonal antibodies (mAbs) that bind to death receptor 4 ("DR4"). The two mAbs were selected from a human phage displayed Fab library by panning against a

recombinant DR4 extracellular domain. Therefore the two mAbs are fully human. These antibodies could have considerable potential as cancer therapeutics alone or in combination with other drugs. Further, these antibodies could be used as a research tool for the study of DR4.

The prospective start-up exclusive commercial license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective start-up exclusive commercial license, may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated start-up exclusive commercial license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: January 24, 2013.

Richard U. Rodriguez, M.B.A.  
Director  
Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

[FR Doc. 2013-02152 Filed 01/31/2013 at 8:45 am; Publication Date: 02/01/2013]